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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,642	03/06/2000	Tongtong Wang	210121.478C4	8132

500 7590 08/27/2003

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

22

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/519,642

Applicant(s)

WANG ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 61,62,65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 61,62,65 and 66 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20. 6) ☐ Other: .

Art Unit: 1631

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/27/2003 has been entered.

Status of Claims

2. It is noted that, although the communication filed 05/27/2003 is titled "Preliminary Amendment", no amendment to the claims or specification is submitted. Claims 61,62,65,66 are pending.

Claim Rejections - 35 U.S.C. § 101/ 112-1

3. Claims 61,62,65,66 remain rejected under 35 U.S.C. § 101. The rejection is maintained for the reasons of record and in view of the following.

Both the response of 05/27/2003 and Declaration of Dr. Wang discuss overexpression of polynucleotides encoding polypeptide SEQ ID 786. Applicant argues that when a DNA is overexpressed, it is reasonable to expect that the corresponding

Art Unit: 1631

protein will be overexpressed also and, therefore, can be used as a diagnostic marker. However, the claims are drawn to polypeptides, rather than to polynucleotides encoding them. There is no information about selective expression of polypeptide SEQ ID 786, or fragments therein, in any tissue, lung cancer tissue in particular. The argument that the gene encoding a polypeptide is selectively expressed or overexpressed in certain tissues does not translate directly into predominant location or overexpression of a corresponding protein. It is known that there is no direct linkage between the levels of DNA and proteins encoded thereby. See, for example, Anderson et al. (Electrophoresis, 1997, 18, 533-537) or Gygi et al. (Molecular and Cellular Biology, 1999, 19, 1720-1730). Hence, it would require further research to establish utility for the claimed polypeptide. Furthermore, additional research will be needed to establish utility for fragments or homologs of the polypeptide SEQ ID No. 786.

Examiner acknowledges clarification that both peptides SEQ ID No. 791 and SEQ ID No. 786 are multiple forms of generically named L522S proteins.

4. Consequently, claims 61, 62, 65,66 also remain rejected under 35 U.S.C. § 112, first paragraph.

Art Unit: 1631

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 20, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.